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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,929

Applicant(s)

HABU ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
4a) Of the above claim(s) 10,17 and 18 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-9 and 11-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on January 30, 2004), Applicants filed a response and amendment received on August 2, 2004 (certified July 29, 2004) with a supplemental response received on November 4, 2004. Said amendment amended Claim 2 and added new Claims 17-18. Claims 1-18 are pending in the instant Office action.

Restriction/Election

2. Claims 1-18 are pending in the instant Office action. Claims 8-16 had been withdrawn from consideration (election without traverse on November 3, 2003); however, since this case is filed in 35 U.S.C. § 121 and 372 (a 371 case), unity of invention must be revisited at each stage of prosecution. The following is the restriction requirement as it stands in the present stage of prosecution:

Group I, claim(s) 1-9 and 11-16, drawn to DNA encoding a protein (SWI2/SNF2-like involved in chromatin remodeling) of at least 150 amino acids of SEQ ID NO:3 within 40% identity, the proteins so encoded, and methods of producing said DNA.

Group II, claim(s) 10 and 17, drawn to a PCR reaction using fragments of SEQ ID NOs: 1 or 2 and RNA that includes fragments of SEQ ID NOs:1 or 2.

Group III, claim(s) 18, drawn to method of releasing silencing in a plant.

Since no prior art was set forth against the DNA claims (1-7), this Group has a special technical feature to share with any methods of making/using and related products. Thus, the proteins encoded by the DNA (Claims 8 and 11-16) share this special technical feature and will

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be examined herein. Also, the method of making the DNA (Claim 9) also shares the special technical feature and will be examined herein.

The products of Group II do not share the special technical feature of Group I because the structure, which is free of the prior art, is not shared with these nucleotide fragment claims. This is clear for Claim 10 (see previously set forth restriction requirement); for Claim 17, neither the full complement nor the complete transcribed mRNA are required and thus the claims read on fragments of the DNA of Claim 1. Since Claim 18 is a method related to Claim 17, it also does not share the special technical feature of Group I. Applicant may traverse the restriction presented above in response to the instant Office action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims of other inventions (Claims 10, 17, and 18) are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Thus, Claims 1-18 are pending. Claims 10, 17, and 18 are withdrawn from consideration as non-elected inventions. Claims 1-9 and 11-16 will be examined herein.

Priority

3. As previously noted, the instant application is the national phase of the International Application No. WO 01/00801 filed on June 21, 2000. The instant application is also granted the benefit of priority for the foreign application 9914623.5 filed in the United Kingdom on June 23, 1999.

Compliance with the Sequence Rules

4. By virtue of the amended sequence listing filed in computer readable form and paper copy on November 4, 2004, as well as by virtue of the amendment to the specification filed on August 2, 2004, the instant application now fully complies with the sequence rules.

Withdrawn - Objections to the Specification

5. Previous objection to the specification for being confusing with respect to the sequence listing is withdrawn by virtue of Applicant's pointing to the mention of SEQ ID NOs: 26-33 on page 14 of the specification as originally filed.

Maintained - Objections to the Specification

6. Previous objection to the specification for missing an abstract is maintained but altered. The Abstract filed in response is objected to for being unclear and not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). The Abstract must describe that which is in the specification in its entirety and not just repeat Claim 1. The reference to SEQ ID NO:3 is unclear as abstract databases will not provide such information. It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source species, *Arabidopsis thaliana* for completeness. An abstract on a separate sheet is required.

7. Previous objection to the specification for inappropriate notation of an internet address is maintained. Applicant's amendment does not obviate this objection. No date retrieved is included as required by M.P.E.P. § 707.05(e). Since BLAST 2.0 is a commonly known tool

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among skilled artisans, the Examiner suggests deleting the internet address altogether to obviate the instant objection.

New - Claim Objections

8. Claim 1 is objected to for having improper grammar. The lack of an article before the singular "transcriptional gene silencing system" is objected to. The article ---a--- should be inserted. Correction is required.

9. Claim 2 is objected to for having a typographical error. The second - should read ---R1 and R3---, as previously claimed and as found in the specification on page 3. Correction is required.

10. Claims 8 and 11-16 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claimed proteins are not within the scope of the invention of the DNA of Claim 1. Independent claim structure is required for Claim 8, at least.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

11. Previous rejection of Claim 7 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of the Examiner's reconsideration in light of Applicant's arguments.

New - Claim Rejections - 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 3 and 12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 3, the limitation that the term “SWI2/SNF2-like ATPase/helicase motifs” is unclear. On page 5 of the specification, a particular portion of SEQ ID NO:3 is described as aligning to part of the ATPase/helicase domain of proteins in the SWI2/SNF2 family; however, no clear indication of what “like” in the term encompasses is set forth. How similar must the sequence be to known ATPase/helicase domains of proteins in the SWI2/SNF2 family? Clarification is required.

13. Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The requirement to optionally “further processing” of the DNA is unclear. What limitation does this require? Since the claim is drawn to a method having open method steps (“comprising”), this last step seems extraneously in its broadest reasonable interpretation. Clarification is required.

New or Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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14. Previous rejection of Claims 1-4 and 7 under 35 U.S.C. § 112, first paragraph, written description, is maintained and amended herein to include Claims 8, 9, 11-13, and 16 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Reasoning is also amended below by virtue of Applicant's amendment.

Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the amendment to include a function has obviated the instant rejection; the Examiner disagrees as evidenced by the rejection below and the new reasoning.

Claim 1 is drawn to DNA encoding a protein having a defined structure (or genus of structures) without a specific function.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical

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characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification teaches SEQ ID NO:3, a protein useful in the silencing of a particular *A. thaliana* gene locus, that which has been altered in ecotype Zurich to contain multiple copies of a hygromycin resistance gene for easy screening (see Example 1). The specification has fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and specific functional limitations (i.e., having the same effect as SEQ ID NO:3 on gene silencing). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having any gene silencing function on any loci in any organism. No correlation between the structure of SEQ ID NO:3 and its function in gene silencing has been described in the instant specification or the art. Therefore, Applicants have not fully described a genus that has sequence identity limitations in the absence of specific functional limitations.

The protein claims are included for reasons analogous to the rejection of the DNA claims above. The method claim (Claim 9) is included because the product made must have adequate written description. *University of Rochester v. G.D. Searle & Co.* (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using (or making) products, wherein said products lack adequate written description.

15. Previous rejection of Claims 1-4 and 7 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while possibly being enabling for any DNA encoding SEQ ID NO:3, does not reasonably provide enablement for DNA encoding a protein structurally related to SEQ ID NO:3 having any specific function is maintained and amended herein to

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include Claims 8, 9, 11-13, and 16 because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. To make and use the invention to the extent of the claimed scope would require undue experimentation. Reasoning is also amended below by virtue of Applicant's amendment.

Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the amendment to include a function has obviated the instant rejection; the Examiner disagrees as evidenced by the rejection below and the new reasoning.

The factors to be considered in determining whether undue experimentation is required are summarized in the previous Office action.

The instant specification teaches SEQ ID NO:3, a protein useful in the silencing of a particular *A. thaliana* gene locus, that which has been altered in ecotype Zurich to contain multiple copies of a hygromycin resistance gene for easy screening (see Example 1). The instant claims are drawn to a large genus of DNA encoding proteins loosely structurally related to SEQ ID NO:3. Copious amounts of experimentation would be necessary to construct all the members of the genus considering only structure. Little guidance is provided for the production of the large and varied genus having the noted function, particularly in its broad description as found in Claim 1. No guidance is provided for DNA that encode proteins having the same function as SEQ ID NO:3 since there is no discussion of the correlation of the structure of SEQ ID NO:3 and its function. The nature of the invention is such that the structure of the DNA is integrally related to its being able to encode a protein of specific function, and in the instant claims the

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structure is extremely varied and the function is not specific. Little work has been done in the field of gene silencing. One of skill in the art would be unable to predict the structure and/or function of all the members of the genus. Thus, the instant claims are not enabled to the full extent of their scope.

Withdrawn - Claim Rejections - 35 U.S.C. § 101

16. Previous rejection of Claims 1-7 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn by virtue of Applicant's amendment to Claim 1 to insert "isolated".

New - Claim Rejections - 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

17. Claims 8 and 11-16, as written, do not sufficiently distinguish over protein as it naturally exists because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g. by insertion of "isolated" or "purified" as taught by the specification. See M.P.E.P. § 2105.

18. Claims 1-9 and 11-16 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility. To fulfill the utility requirement of 35 U.S.C. § 101, an invention must

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have a specific, substantial, and credible utility, which is disclosed in the specification or which is well established as considered by one of ordinary skill in the art.

The instant claims are drawn to gene silencing proteins, the DNA that encode them, and methods of making said DNA. A particular protein, SEQ ID NO:3, is taught as silencing a particular locus of *A. thaliana*, at least that is how the Examples in the specification describe finding said protein. Page 2 of the specification also describes the function of the identified protein in vague terms. No description of this locus and why one might want to silence it is found in the specification. No description of how broadly SEQ ID NO:3, or related sequences, can be used is found, i.e., if it can be used to silence other loci of *A. thaliana* that contain genes whose silencing would be considered useful. With such little known in the art about gene silencing and its applicability, the genus of proteins claimed, for example see Claim 8, lacks utility. The species of SEQ ID NO:3 also lacks utility because no real world use has been proposed or found in the art. While further experimentation may be considered with this knowledge in hand, to meet the requirements for utility require a real world use. Thus, the usefulness of even exactly SEQ ID NO:3 (and the exactly encoding SEQ ID NOs: 1 and 2) is unclear.

Comments Concerning Related Art

19. As previously noted, GenBank Accession Numbers B20116 and B67281 (both in Applicants' IDS) teach *Arabidopsis* DNA sequences with high similarity to SEQ ID NO:2 and/or encoding SEQ ID NO:3. However, neither sequence teaches DNA encoding a long enough open reading frame. For example, for B20116, stop codons are 121 codons apart. So although these codons are highly similar to a DNA encoding SEQ ID NO:3, the DNA does not meet all the

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limitations of Claim 1. Moreover, the structurally specific sequence of Claims 5 and 6 are free of the prior art.

Conclusion

20. Claims 1-9 and 11-16 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **non-final** based on the new grounds of rejection presented herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

February 3, 2005